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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,678	09/15/2003	John P. Troup	8493-US	1877
74476	7590	02/24/2009		
Nestle HealthCare Nutrition 12 Vreeland Road, 2nd Floor, Box 697 Florham Park, NJ 07932			EXAMINER	
			HA, JULIE	
			ART UNIT	PAPER NUMBER
			1654	
			NOTIFICATION DATE	DELIVERY MODE
			02/24/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdepartment@nestle.com  
athena.pretory@us.nestle.com

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p><b>Application No.</b> 10/662,678</p>	<p><b>Applicant(s)</b> TROUP ET AL.</p>	
	<p><b>Examiner</b> JULIE HA</p>	<p><b>Art Unit</b> 1654</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 06 February 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): 35 U.S.C. 112, second paragraph.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-4, 7-11, 13, 14, 16, 17 and 23-28.  
Claim(s) withdrawn from consideration: 6, 12 and 18-22.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
Please see continuation of 11.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

/Cecilia Tsang/  
Supervisory Patent Examiner, Art Unit 1654

Continuation of 11:

Objection on Page 4 of the claims is hereby withdrawn in view of Applicant's amendment to the claims.

Rejection of claims 3, 16 and 25 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as being indefinite, is hereby withdrawn in view of Applicant's arguments and amendment to the claims.

**Maintained Rejections:**

Claims 3-4, 7-11, 13-14, 16 and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Abbruzzese et al (US Patent No. 6,387,883) as set forth in the previous office action.

Applicant argues that "Abbruzzese fails to disclose or suggest that leucine, in free and/or salt form, is present in an amount of at least about 25 % by weight based on the weight of intact protein as required by independent claim 3." Applicant further argues that "In the only example that utilizes leucine, Abbruzzese teaches an amino acid profile for his nutritional composition with leucine in an amount of 9.08 g/100g protein (i.e. 9.08%), which is substantially lower than that of the present claims."

Applicant's arguments have been fully considered but have not been found persuasive. As described in the previous office action, it would have been obvious to one of ordinary skill in the art to optimize the conditions of Abbruzzese et al to produce a nutritional composition comprising essential and non-essential amino acids and PUFA such as EPA, since the prior art teaches a nutritional composition for treating cancer cachexia. There is a reasonable expectation of success, since "it is the normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine wherein a disclosed set of percentage ranges is optimum combination of percentages". One of ordinary skill in the art would have been motivated to optimize the concentration of each component for the optimal nutritional composition. All of the components to the nutritional composition recited in the instant claims are disclosed in the reference. It would have been obvious to one of ordinary skill in the art to optimize the concentration disclosed in the reference to obtain the best nutritional composition. Therefore, there is a reasonable expectation of success to optimize the concentration of the tocopherol and leucine and other essential amino acid concentration, since one of ordinary skill in the art would experiment with different concentrations to produce the optimal product.

Claims 1-2 and 23-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen et al (US Patent No. 4,898,879) as set forth in the previous office action.

Applicant argues that "Madsen fails to disclose or suggest that leucine, in free and/or salt form, is present in an amount of at least 25% to about 95% by weight based on the weight of total amino acids as required by independent claims 1-2. Madsen also fails to disclose or suggest that leucine, in free and/or salt form, is present in an amount of at least 25% by weight based on the weight of total amino acids as required by independent claims 23-24." Applicant further argues that "leucine is one of many listed amino acids and Madsen fails to recognize or suggest any superior benefit from increased levels of leucine beyond what is taught."

Applicant's arguments have been fully considered but have not been found persuasive. As described in the previous office action, it would have been obvious to one of ordinary skill in the art to optimize the conditions of Madsen et al to produce a nutritional composition comprising essential and non-essential amino acids, since the prior art teaches nutritional composition for treating different disorders. Madsen teaches nutritional compositions comprising L-leucine (about from 19.4 to 19.8). Both the reference and the instant claims recite, "about" in regard to the amount of leucine content ("at least about 25% to about 95%" for instant claims, and "about from 19.4 to 19.8%" from Madsen reference). Further more, the reference teaches that the essential amino acids should comprise about from 60 to 75% by weight of the total amino acids in the composition. This is within the limit of ratio of from about 0.6 to about 0.90. The ordinary skill in the art would have been motivated to optimize the essential amino acid concentration in the nutritional composition to achieve the optimal nutritional composition. Therefore, there is a reasonable expectation of success to optimize the concentrations of the tocopherol and essential amino acid concentrations, as one of ordinary skill in the art would experiment with different concentrations to produce the optimal product.

Claims 3-4, 7, 17, 25 and 27-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hageman et al (US Patent No. 6,420,342) in view of Salvati et al (US Patent No. 6,953,679).

Applicant argues that "Hageman and Salvati fails to disclose or suggest leucine, in free and/or salt form, is present in an amount of at least about 25% by weight based on the weight of intact protein as required by independent claims 3, 17, 25 and 28. Hageman and Salvati also fail to disclose or suggest a ratio of total essential amino acids and, optionally, conditionally essential amino acids to total amino acid ranging from about 0.60 to about 0.90 as required by independent claims 3, 17, 25 and 28.

Applicant's arguments have been fully considered but have not been found persuasive. As described in the previous office action, it would have been obvious for one of ordinary skill in the art to combine the teachings of Hageman et al and Salvati et al to produce a kit comprising the anti-cancer agent with the nutritional composition, since Salvati et al teach a kit comprising fused cyclic compound, nutritional supplement comprising leucine, whey and protein and any anti-cancer agent and Hageman et al teach the nutritional composition. One of ordinary skill in the art would be motivated to combine, since Salvati et al teaches such a composition/kit. Hageman teaches that in supplements for sportsmen and persons that temporarily require high protein requirements, up to 60g of protein per daily dose can be included. Therefore, it would have been obvious to one of ordinary skill in the art to optimize the concentrations of the essential amino acids to achieve the optimal nutritional composition. Essential amino acids added together would add up to 0.80, which is within the range of 0.60 and 0.90. Salvati teaches a nutritional supplement and a kit comprising a first container containing a pharmaceutical

formulation comprising a compound, a second container containing a pharmaceutical formulation comprising one or more agents to be used in combination with the compound of the invention. Therefore, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Conclusion:

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Examiner, Art Unit 1654